PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

United States Patent and Trademark Office
(Box PCT)
Crystal Plaza 2
Washington, DC 20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 07 June 1999 (07.06.99)	
International application No. PCT/US98/18953	**Applicant's or agent's file reference** 719-75PCT
International filing date (day/month/year) 11 September 1998 (11.09.98)	**Priority date** (day/month/year) 11 September 1997 (11.09.97)
Applicant ACHARI, Raja, G. et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

30 March 1999 (30.03.99)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Jocelyne Rey-Millet
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: KIRK M. MILES
HOFFMANN & BARON, LLP
6900 JERICHO TURNPIKE
SYOSSET, NEW YORK 11791

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing *(day/month/year)*	23 DEC 1999
Applicant's or agent's file reference: 719-75PCT	IMPORTANT NOTIFICATION

International application No.	International filing date *(day/month/year)*	Priority Date *(day/month/year)*
PCT/US98/18953	11 SEPTEMBER 1998	11 SEPTEMBER 1997

Applicant
NASTECH PHARMACEUTICAL COMPANY, INC.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	M. MOEZIE
Facsimile No. (703) 305-3230	Telephone No. (703) 308-1235

Form PCT/IPEA/416 (July 1992)★

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: KIRK M. MILES
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Date of Mailing *(day/month/year)*	23 DEC 1999

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719-75PCT	

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Name and mailing address of the IPEA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	M. MOEZIE
Facsimile No. (703) 305-3230	Telephone No. (703) 308-1235

Form PCT/IPEA/416 (July 1992)*

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
719-75PCT		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US98/18953	11 SEPTEMBER 1998	11 SEPTEMBER 1997
International Patent Classification (IPC) or national classification and IPC IPC(6): A61K 31/44 and US Cl.: 514/291		
Applicant NASTECH PHARMACEUTICAL COMPANY, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets.

   [✓] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I [X] Basis of the report
   - II [ ] Priority
   - III [ ] Non-establishment of report with regard to novelty, inventive step or industrial applicability
   - IV [ ] Lack of unity of invention
   - V [X] Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI [ ] Certain documents cited
   - VII [ ] Certain defects in the international application
   - VIII [ ] Certain observations on the international application

Date of submission of the demand	Date of completion of this report
30 MARCH 1999	20 NOVEMBER 1999
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer M. MOEZIE
Facsimile No. (703) 305-3230	Telephone No. (703) 308-1235

Form PCT/IPEA/409 (cover sheet) (January 1994)*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US98/18953

I. Basis of the report

1. This report has been drawn on the basis of *(Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments).*

☐ the international application as originally filed.

☒ the description, pages (See Attached), as originally filed.
pages _____, filed with the demand.
pages _____, filed with the letter of _____.
pages _____, filed with the letter of _____.

☒ the claims, Nos. (See Attached), as originally filed.
Nos. _____, as amended under Article 19.
Nos. _____, filed with the demand.
Nos. _____, filed with the letter of _____.
Nos. _____, filed with the letter of _____.

☒ the drawings, sheets/~~fig~~ (See Attached), as originally filed.
sheets/~~fig~~ _____, filed with the demand.
sheets/~~fig~~ _____, filed with the letter of _____.
sheets/~~fig~~ _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☒ the description, pages NONE.

☒ the claims, Nos. NONE.

☒ the drawings, sheets/~~fig~~ NONE.

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the ~~Supplemental Box~~ Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:

NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US98/18953

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims	1-21	YES
	Claims	NONE	NO
Inventive Step (IS)	Claims	1-21	YES
	Claims	NONE	NO
Industrial Applicability (IA)	Claims	1-21	YES
	Claims	NONE	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-21 meet the criteria set out in PCT Article 33(2), because the prior art does not teach the scopolamine containing intranasal compositions or methods of treatment.

Claims 1-21 meet the criteria set out in PCT Article 33(4), because the claimed scopolamine containing intranasal compositions and methods of treatment have industrial applicability in the pharmaceutical art.

Claims 1-21, as amended 18 Oct 1999, meet the criteria set out in PCT Article 33(3) since the claimed scopolamine containing intranasal compositions and methods of treatment possess an inventive step. Applicant's remarks and Exhibits A and B submitted 18 Oct 1999 relating to the nonobviousness of the inclusion of PVA in the intranasal compositions herein wherein the composition pH is below about 4.0, are persuasive.

---------- NEW CITATIONS ----------

NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US98/18953

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

I. BASIS OF REPORT:

This report has been drawn on the basis of the description,
pages, 1-33, as originally filed.
pages, NONE, filed with the demand.
and additional amendments:
NONE

This report has been drawn on the basis of the claims,
numbers, NONE, as originally filed.
numbers, NONE, as amended under Article 19.
numbers, NONE, filed with the demand.
and additional amendments:
Claims 1-21, filed with the letter of 18 October 1999.

This report has been drawn on the basis of the drawings,
sheets, 1-2, as originally filed.
sheets, NONE, filed with the demand.
and additional amendments:
NONE

WHAT IS CLAIMED IS:

1. An intranasal formulation comprising scopolamine in a pharmaceutically acceptable carrier at a pH below about 4.0 and a buffer salt concentration below about 200 mM, said carrier incorporating polyvinyl alcohol.

2. An intranasal formulation as in claim 1, wherein said carrier is a pharmaceutically acceptable gel.

3. An intranasal formulation as in claim 1, wherein said polyvinyl alcohol is combined with one or more additional gelling agents or bio-adhesives selected from the group including alginates, gums, starches, polyacrylates, dextrans, chitosans and mixtures thereof.

4. An intranasal formulation as in claim 1, wherein said concentration is at or below about 100 mM.

5. An intranasal formulation as in claim 1, wherein said concentration is at or below about 50 mM.

6. An intranasal formulation as in claim 1, wherein said pH is about 3.5.

7. An intranasal formulation as in claim 1, wherein said scopolamine is provided as a chemically modified equivalent or pharmaceutically acceptable salt thereof.

8. An intranasal formulation as in claim 7, wherein said scopolamine is provided as scopolamine hydrobromide.

9. An intranasal formulation for preventing and/or treating nausea and/or vomiting described in claim 1.

10. An intranasal formulation as in claim 1 further including buffering agents, thickening agents, tolerance enhancers, surfactants, excipients, preservatives and combinations thereof.

11. An intranasal gel formulation for preventing and/or treating motion sickness comprising scopolamine hydrobromide in a gel solution at or below a pH at about 3.5 and a buffer salt concentration at or below about 100 mM, said gel solution incorporating polyvinyl alcohol as a gelling agent.

12. An intranasal formulation as in claim 11, wherein said gel solution further includes gelling agents and/or bio-adhesives selected from the group including alginates, gums, starches, polyacrylates, dextrans, chitosans and mixtures thereof.

13. An intranasal gel formulation as in claim 11 further including buffering agents, thickening agents, tolerance enhancers, surfactants, excipients, preservatives and combinations thereof.

14. A method of preventing and/or treating nausea and/or vomiting comprising administering intranasally to a mammal an effective amount of scopolamine, chemically modified equivalents and pharmaceutical salts thereof in a pharmaceutically acceptable carrier at a pH below about 4.0 and a buffer salt concentration below about 200 mM, said carrier incorporating polyvinyl alcohol.

15. A method as in claim 14, wherein said carrier further includes gelling agents and/or bio-adhesives selected from the group including alginates, gums, starches, polyacrylates, dextrans, chitosans and mixtures thereof.

16. A method as in claim 14, wherein said carrier is a gel for intranasal administration.

17. A method as in claim 14, wherein said salt concentration is at or below about 100 mM.

18. A method as in claim 14, wherein said salt concentration is at or below about 50 mM.

19. A method as in claim 14, wherein said pH is about 3.5.

20. A method as in claim 14, wherein said scopolamine is provided as scopolamine hydrobromide.

21. A method as in claim 14, wherein a nausea and/or vomiting preventing or treating scopolamine free base plasma concentration is achieved within about 5 minutes.